

General European OMCL Network (GEON) QUALITY MANAGEMENT DOCUMENT

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EXTERNALLY PROVIDED PRODUCTS AND SERVICES

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Concerned Network	GEON

N.B. This OMCL Quality Management System document is applicable to members of the European OMCL Network only. Other laboratories might use the document on a voluntary basis. However, please note that the EDQM cannot treat any questions related to the application of the documents submitted by laboratories other than the OMCLs of the Network.

EXTERNALLY PROVIDED PRODUCTS AND SERVICES

GUIDELINE FOR OMCLs

Note: Mandatory requirements in this guideline and its annexes are defined using the terms “shall” or “must”. The use of “should” indicates a recommendation. For these parts of the text other appropriately justified approaches are acceptable. The term “can” indicates a possibility or an example with non-binding character.

1. SCOPE

This document provides guidance to an Official Medicines Control Laboratory (OMCL) when externally provided products and services affecting laboratory activities are used, with a special focus on the testing services.

The scope covers externally provided products, which can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials and externally provided services that can include, for example, testing services, calibration services, facility and equipment services, proficiency testing services and assessment and auditing services.

The document describes how the defining, reviewing and approving of laboratory requirements and evaluation, selection, monitoring and re-evaluation of the external providers should be handled. Concerning the testing services also informing the customer about outsourced work and reporting of test results are covered. For OCABR and the MRP/DCP testing program of the OMCL Network, special provisions concerning outsourcing of testing activities are in place.

Besides this Guideline, the OMCLs shall have a procedure to manage external providers of products and services that affect laboratory activities, including the retention of records.

The core document is complemented with two annexes with examples on qualification of testing service providers and model contract for outsourcing testing services. Annexes have non-binding character.

2. INTRODUCTION

The OMCL shall ensure that only suitable externally provided products and services that affect laboratory activities are used when such products and services are intended for incorporation into the laboratory's own activities and are used to support the operation of the laboratory.

The assessment of adequacy of resources for testing shall be included in the Management Review.

This review can result in a decision to temporarily or permanently outsource certain testing and/or calibration services. The external service provider can be any laboratory that meets the pre-defined requirements of the OMCL such as another OMCL, a regulatory (government) laboratory, a laboratory at a university or a commercial provider.

The reasons for outsourcing activities can include, for example:

- Special technique/equipment not available in the OMCL (e.g. animal testing for OCABR, NMR)
- Confirmatory testing by a second laboratory
- Work-sharing (e.g. in cases of pandemics)
- Excessive workload
- Lack of qualifications, competency or resources
- Very low number of tests per year

In the specific case of testing, the service providers can be divided into:

- OMCL Network members
- Accredited laboratories outside of the OMCL Network
- Non-accredited laboratories outside of the OMCL Network.

Possible situations regarding outsourcing of testing activities include:

- OMCL-OMCL on a regular, temporary or work-sharing basis
- OMCL-others (a government laboratory, a laboratory in the same organization that is not a member of the OMCL Network, a university laboratory or a commercial provider).

In all these situations, evidence of the external providers conformity to the laboratory's requirements and whenever applicable the evidence for compliance with ISO/IEC 17025 shall be in place.

In the case of outsourcing of testing services the OMCL must assume responsibility for the results of external service providers with its customers, provided that the selection of the service provider has been performed by the OMCL.

3. SELECTION OF EXTERNAL PROVIDERS

The OMCL shall define the requirements for externally provided products and services. For this purpose, the OMCL shall define evaluation criteria for selection of the different types of provided products and services. These pre-defined requirements shall be communicated to the possible providers during the selection phase. The criteria can include, for example:

- Required quality for the intended use,
- Price-performance ratio
- Terms and conditions
- Past experiences with a provider
- Delivery times etc.

Additional criteria can apply to the provider, for example,

- Quality management system of the provider
- Legal requirements etc.

The selection of external providers may not always be based on all steps considering the evaluation of the provider.

In the case the OMCL is part of a larger organization, decisions concerning the selection of external providers may be taken at the upper management level. The OMCL should be involved as far as possible in the selection process. Possible risks with providers, which do not comply with the requirements of the OMCL, shall be part of the risk management.

When external providers are operating in compliance with the relevant ISO Norm or accredited for the specific service requested they are considered competent. For specific products and services, the following standards apply and should be considered by the OMCL:

- For reference material producers the requirements of ISO 17034,
- For the providers of Proficiency Testing Studies (PTS) the requirements of ISO/IEC 17043,
- For the providers of calibration services the requirements of ISO/IEC 17025.

The selection of a suitable provider for an equipment is part of Level I "Selection of instruments and suppliers" in an equipment qualification process (PA/PH/OMCL (08) 73 Qualification of Equipment – Core Document).

In the selection process for providers of testing services the following points should be considered:

- It should include criteria based on technical and any additional requirements, and should include the defined criteria in ANNEX I, "Qualification of Testing Service Provider" PA/PH/OMCL (14) 39 in its current version.
- When outsourcing testing from an OMCL, the OMCL Inventory Database can be a helpful tool to collect information about potential laboratories and their competences.
- The responsibilities listed in the ANNEX II, "Principles of contracting the testing service provider and OMCL Model contract for outsourcing of testing services" PA/PH/OMCL (14) 40 in its current version should also be taken into account.
- The final decision to select a provider of testing services can be based on the information provided of a submitted questionnaire, an audit, witness testing and/or other means used to collect information relevant to test performance. Whichever approach is taken, there must be evidence/records that the laboratory is suitable to provide the expected level of performance, in relation to the other available providers and taking into consideration the criticality of the service.
- After a critical evaluation of the information collected, the OMCL should decide whether the proposed service provider is suitable for the laboratory work.

Approval from customers must be obtained before work is outsourced, whenever applicable. Providing that the Competent Authority is the customer, evidence shall be available that using an external testing

service provider was approved or that the OMCL has been mandated to outsource testing without formal approval of their Competent Authority.

Reporting of the results from testing service provider

On reports issued to customers, the laboratory must clearly indicate if a test was performed by an external testing service provider.

For market surveillance, the Competent Authority is generally considered the customer (e.g. inspectorate of a medicines agency). For OCABR, both the manufacturer and the member state (competent authority) can be considered as clients since although the manufacturer makes the request for testing it is at the demand of the member states who require OCABR. However, according to the provisions related to OCABR, advance approval for using an external service provider by the MAH is generally not required and it is not obligatory to include the information on the OCABR certificates. OMCLs performing OCABR are either Competent Authorities or are mandated by a Competent Authority to carry out batch release, and this should also be taken into account when approving outsourcing of testing.

4. EVALUATION, MONITORING AND RE-EVALUATION OF THE PERFORMANCE OF THE EXTERNAL PROVIDERS

The OMCL shall define criteria to evaluate and monitor the quality of the products and services and the performance of external providers.

The following criteria can be applied for evaluation and monitoring the performance of an external provider:

- Quality of products or services
- Timeliness
- Conformity of supply in relation to orders
- Customer friendliness
- Price policy
- Goodwill
- Terms and conditions etc.

Evaluation and monitoring of the products and services and their providers are permanent activities as every delivery is evaluated, at least in relation to its conformity to the order.

Outsourced work should be reviewed by the contracting OMCL after receipt of each report and in light of the documented evidence of the outsourcing and the service outcome.

The OMCL should define products and services and providers of products and/or service for which the monitoring is performed more thoroughly or for which periodic re-qualifications are necessary. They can include:

- Providers of critical services (e.g. calibration services; suppliers of reference standards)
- New providers
- Providers with a history of non-conforming supply
- Providers of testing services

The OMCL should not place an order to a provider that has been identified as non-satisfactory by previous evaluations. The OMCL should try to organize a specific arrangement in order to solve the issues so that the quality of the planned services is at required level or, if this is not possible, to find another provider. The qualification of an accredited provider of testing / calibration services, PTS or reference materials is valid as long as the corresponding accreditation certificate is valid. That means, for example, that a provider of calibration services must be re-qualified, if the date of "valid until" on the certificate is expired.

The OMCL shall address the consequences when problems with a provider of products or services occur and shall take appropriate actions to control and correct the non-conformities. Complaints in relation with the performance of providers of products and services shall be included as information during the management review.

5. REFERENCES

- ISO/IEC 17025:2017 (6.6 / 7.1.1, others) "General requirements for the competence of testing and calibration laboratories"
- PA/PH/OMCL (07) 79 "Terms of reference for the General European OMCL Network (GEON) of the Council of Europe", in its current version
- PA/PH/OMCL (10) 25 "OCABR: Terms of reference" in its current version
- PA/PH/OMCL (06) 35 "OCABR Subcontracting activities between OMCL's"
- PA/PH/OMCL (06) 102 DEF ANNEX II "Model Agreement letter for subcontracting between OMCL's" (for OCABR)
- PA/PH/OMCL (06) 116 "Co-operation in post-marketing surveillance of MRP/DCP products", in its current version
- PA/PH/OMCL (08) 73 "Qualification of Equipment –Core Document"